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(54) FORMULATION FOR TREATING OBESITY AND ASSOCIATED METABOLIC SYNDROME

FORMULIERUNG ZUR BEHANDLUNG VON FETTLEIBIGKEIT UND ASSOZIIERTEM STOFFWECHSELSYNDROM

FORMULATION DESTINEE AU TRAITEMENT DE L'OBESITE ET DU SYNDROME METABOLIQUE ASSOCIE

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[0040] After 14 weeks, body weight decrease was equal 6.06 % in the control group and 9,28 % in the treated group which was receiving the formulation of the invention (fig. 5). Those values expressed in kilograms are equal to 5.54 kg and 8.51 kg respectively. Difference between these two groups was 53.6 %. Differences were found statistically significant.
[0041] Decrease of body fat concentration was equal to -4.0 kg in the control group and -6.6 kg in the treated group (fig 6). Simultaneously, decrease of LDL plasma cholesterol concentration by 1.58 mg/dl in the control group and by 6.08 mg/dl in the treated group (fig.7) and total plasma cholesterol by 3.92 mg/dl and 19.42 mg/dl (fig.8) respectively was observed. Reduction of cholesterol concentration was accompanied by decrease of plasma triglyceride concentration by 6.63 mg/dl in the treated group, while in the control group triglyceride concentration increased by 1.42 mg/dl (fig.9).
[0042] The quoted studies have verified

a) Formulation of the invention is accelerating weight loss during dietary treatment of obesity.
b) Formulation of the invention contains active components which effects are synergistically strengthening each other, so that effect of their mixture is significantly greater them the effect of any separate component alone.

Claims

1. Formulation for treating obesity and associated metabolic syndrome, comprising a combination of vegetable extracts, **characterized in that** it consists of:

   a) 20-90% wt. of Green tea extract, containing more than 70 % of catechines, preferably containing Epigallocatehin galate (EGCG),
   b) 2-30 % wt. of *Coleus forskholii* extract, containing at least 10 % of diterpene forskolin,
   c) 5-58 % wt. of Yerba Maté extract, containing 2-4 % of caffeine and caffeoylquinic acids (CGA),
   d) 7.5-45 wt. of *Betula alba* extract containing at most 3% of flavonides.

2. Formulation according to claim 1, **characterized in that** it further comprises an effective amount of vegetable extract of white kidney beans (*Phaseolus Vulgaris*).

3. Formulation according to claim 1 or 2, **characterized in that** Green tea extract is an extract obtained by water and/or ethyl acetate and water extraction in low temperature under reduced pressure.

4. Formulation according to claim 1 or 2, **characterized in that** Green tea extract is an extract obtained by alcohol extraction or extraction conducted in the presence of fat solvents for example selected from a group consisting of: methanol-chloroform mixture, alcohol ethers and detergents, in low temperature under reduced pressure.

5. Formulation according to claim 3 or 4, **characterized in that** Green tea extract comprises at least 30 % of EGCG

6. Formulation according to claim 3 or 4, **characterized in that** Green tea extract comprises at least 50 % of EGCG

7. Formulation according to claim 3 or 4, **characterized in that** Green tea extract comprises at least 80 % of EGCG

8. Formulation according to any of the claims 1-7, **characterized in that** it further comprises non-active exicipients or fillers selected from a group consisting of: silicon dioxide, magnesium stearate, laurylsulphate, other surfactants for example selected from a group consisting of: sodium carboxymethylcellulose, hydroxypropylmethyl cellulose and microcrystalline cellulose, anty-caking agents such as dicalcium phosphate; and materials forming the shell of the capsule.

9. Formulation for treating obesity and associated metabolic syndrome, comprising a combination of selected vegetable extracts, **characterized in that** it consists of:

   a) 20-80% wt. of Green tea extract, containing more than 70 % of catechines, preferably containing Epigallocatehin galate (EGCG),
   b) 2-30 % wt. of *Coleus forskholii* extract, containing at least 10 % of diterpene forskolin.
   c) 5-50 % wt. of Guarana extract, containing more than 8 % of caffeine and caffeine-like polyphenoles (chlorogenic acids - CGA)
   d) 7.5-45 % wt. of *Betula alba* extract containing at most 3% of flavonides.

10. Formulation according to claim 9, **characterized in that** it further comprises an effective amount of vegetable extract of white kidney beans (*Phaseolus Vulgaris*).

11. Formulation according to claim 9 or 10, **characterized in that** Green tea extract is an extract obtained by water and/or ethyl acetate and water extraction in low temperature under reduced pressure.

12. Formulation according to claim 9 or 10, **characterized in that** Green tea extract is an extract obtained by alcohol extraction or extraction conducted in the presence of fat solvents for example selected from a group consisting of: methanol-chloroform mixture, alcohol ethers and detergents, in low temperature under reduced pressure.

13. Formulation according to claim 11 or 12, **characterized in that** Green tea extract comprises at least 30 % of EGCG

14. Formulation according to claim 11 or 12, **characterized in that** Green tea extract comprises at least 50 % of EGCG

15. Formulation according to claim 11 or 12, **characterized in that** Green tea extract comprises at least 80 % of EGCG

16. Formulation according to any of the claims 9-15, **characterized in that** it further comprises non-active exicipients or fillers selected from a group consisting of silicon dioxide, magnesium stearate, laurylsulphate, other surfactants for example selected from a group consisting of: sodium carboxymethylcellulose, hydroxypropylmethyl cellulose and microcrystalline cellulose, anty-caking agents such as dicalcium phosphate; and materials forming the shell of the capsule.

Patentansprüche

1. Formulierung zur Behandlung von Fettleibigkeit und assoziiertem Stoffwechselsyndrom, mit einer Kombination von Gemüseextrakten, **dadurch gekennzeichnet, dass** sie besteht aus:

   a) 20 bis 90 Gewichtsprozent Extrakt von Grünem Tee, mit mehr als 70 % Katechinen, vorzugsweise enthalten Epicallocatehingallat (EGCG),
   b) 2 - 30 Gewichtsprozent Extrakt von *Coleus Forskholii*, mit wenigstens 10 % Diterpenforskolin,
   c) 5 - 58 Gewichtsprozent Extrakt von Yerba Mate, mit 2 - 4 % Koffein und Kaffeeoylquiniksäuren (CGA),
   d) 7,5 - 45 Gewichtsprozent Extrakt von *Betula Alba*, mit höchstens 3 % Flavoniden.

2. Formulierung nach Anspruch 1, **dadurch gekennzeichnet, dass** sie außerdem eine wirksame Menge eines Gemüseextrakts von weißen Bohnen (*Phaseolus Vulgaris*) enthält.

3. Formulierung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** das Extrakt von Grünem Tee ein Extrakt ist, welches durch Wasser und/oder Ethylacetat und eine Wasserextraktion bei niedriger Temperatur unter vermindertem Druck erhalten wird.

4. Formulierung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** das Extrakt von Grünem Tee ein Extrakt ist, welches durch Alkoholextraktion oder durch eine Extraktion, welche in Gegenwart von Fettlösern durchgeführt wird, welche beispielsweise ausgewählt sind aus einer Gruppe, welche aus einer Methanol-Chloroform-Mischung, Alkoholethern und Detergentien besteht, bei niedriger Temperatur unter vermindertem Druck, erhalten wird.

5. Formulierung nach Anspruch 3 oder 4, **dadurch gekennzeichnet, dass** das Extrakt von Grünem Tee wenigstens 30 % EGCG enthält.

6. Formulierung nach Anspruch 3 oder 4, **dadurch gekennzeichnet, dass** das Extrakt von Grünem Tee wenigstens 50 % EGCG enthält.

7. Formulierung nach Anspruch 3 oder 4, **dadurch gekennzeichnet, dass** das Extrakt von Grünem Tee wenigstens 80 % EGCG enthält.

8. Formulierung nach einem der Ansprüche 1 bis 7, dadurch, dass sie außerdem nicht aktive Exicipienten oder Füllstoffe aufweist, welche aus einer Gruppe ausgewählt sind, welche besteht aus: Silikondioxid, Magnesiumstearat, Laurylsulphat, anderen oberflächenaktiven Stoffen, beispielsweise ausgewählt aus einer Gruppe, welche besteht aus: